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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,070	07/14/2003	Frederick H. Sklar	B6226.1615.4370	7120

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EXAMINER	
WIEKER, AMANDA F.	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,070	SKLAR ET AL.	
	Examiner	Art Unit	
	Amanda F. Wieker	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☒ Claim(s) *40,41 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The use of the trademark GORE-TEX® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

2. Claim 13 is objected to because of the following informalities:

In the last line of claim 13, it appears that the word --of-- should be inserted between "segment" and "its".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

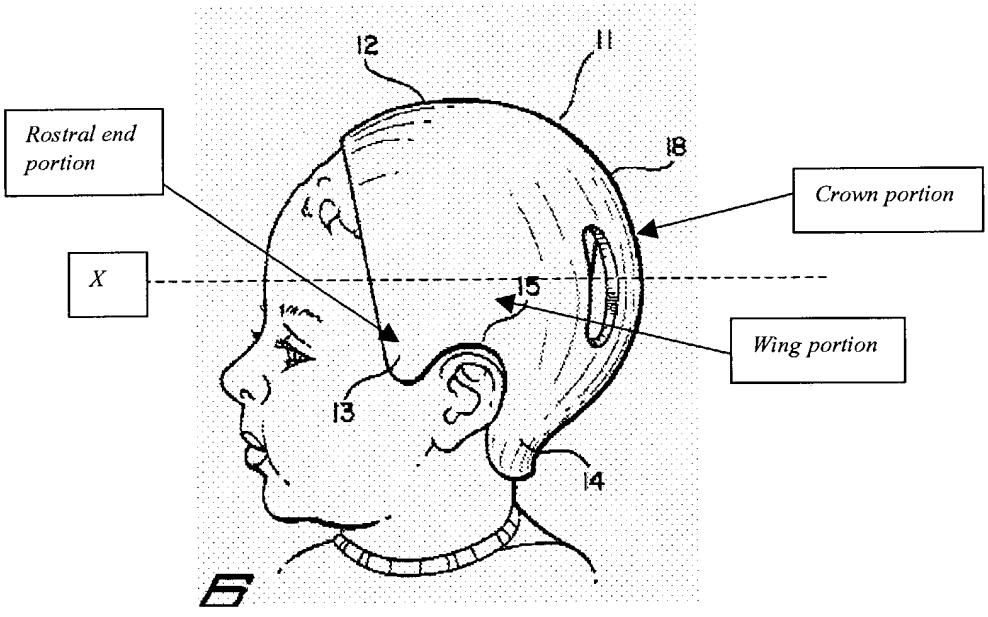
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-31, 35-39, 42 and 45-50 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,951,503 to Pomatto.

Pomatto discloses a cranial orthosis (11) for preventing further acquired or positional plagiocephaly in infants comprising a molded protective shell (16), helmet or headband having an interior surface that is conformed in shape to the surface curvature of a normal human infant cranium, thereby defining a cavity or pocket for receiving the head of an infant having

compliant, developing head areas to be protected, the cavity being sized to provide a close, non-interfering fit of the conformed interior surface in facing relation to the developing head areas to be protected, whereby when an infant's head is received in the protective cavity, the infant's head weight forces can be spread substantially uniformly across the conformed interior surface that engages one or more of the developing head areas while the infant is resting on a sleep surface in a supine position. The protective shell (12) includes interior surfaces that are smoothly contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas (see Figure 6), respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender. The cavity is slightly oversized (at 18) relative to the head of an infant to be protected so that the infant's head can be turned from side-to-side on the sleep surface without imposing binding engagement of the protective shell against the soft developing areas of the infant's head. The protective shell (12) is "loosely" fitted relative to the head of an infant to be protected so that the orthosis can be worn while the infant is resting in a supine position on a sleep surface substantially without imposing torque forces against the soft developing areas of the infant's head, while distributing the infant's head weight forces over a large segment of its cranial vault. The protective shell includes a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions, wherein the wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas of an infant's head when it is received in the protective shell (see below). The rostral end portions are dimensioned to provide at least partial overlapping coverage over an infant's fronto-parietal and temporal areas when it is received in the protective shell, while the crown is dimensioned to provide overlapping coverage

over substantially all of the occipital area of an infant's head when it is received in the protective shell. The wing and rostral portions are dimensioned to provide limited overlapping coverage whereby the upper aspects of the parietal, temporal and frontal bones are only partially covered by the appliance in the protective position, thus allowing good air circulation and heat transfer over most of the infant's head, while preventing uneven contact of the relatively soft, compliant occipital areas against the sleep surface. The shell has a U-shaped cross-section, when taken about line "X," as noted below, and has bilateral symmetry. The shell (16) comprises a unitary vacuum molding formed of plastic resin material, specifically, copolymer polypropylene. The orthosis comprises a layer of soft, flexible material (17) covering the conformed interior surface of the molded appliance. The claimed method is anticipated by the normal use of the orthosis as disclosed by Pomatto.



5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-31, 35-38, 42, and 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 4,776,324 to Clarren.

Clarren discloses a cranial orthosis for preventing positional plagiocephaly in infants comprising a protective shell (70) having an interior surface that is conformed in shape to the surface curvature of a normal human infant cranium, thereby defining a cavity for receiving the head of an infant having compliant, developing head areas to be protected, the cavity being sized to provide a close, non- interfering fit of the conformed interior surface in facing relation to the developing head areas to be protected, whereby when an infant's head is received in the protective cavity, the infant's head weight forces are spread substantially uniformly across the conformed interior surface that engages one or more of the developing head areas while the infant is resting on a sleep surface in a supine position. The protective shell (70) includes interior surfaces that are smoothly contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas (see Figure 5), respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender. The cavity is slightly oversized (again, see Figure 5) relative to the head of an infant to be protected so that the infant's head can be turned from side-to-side on the sleep surface without imposing binding engagement of the protective shell against the soft developing areas of the infant's head. The protective shell (70) is loosely fitted relative to the head of an infant to be protected so that the orthosis can be worn while the infant is resting in a supine position on a sleep surface substantially without imposing torque forces against the soft developing areas of the infant's

head, while distributing the infant's head weight forces over a large segment of its cranial vault. The protective shell includes a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions, wherein the wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas of an infant's head when it is received in the protective shell. The rostral end portions are dimensioned to provide at least partial overlapping coverage over an infant's fronto-parietal and temporal areas when it is received in the protective shell, while the crown is dimensioned to provide overlapping coverage over substantially all of the occipital area of an infant's head when it is received in the protective shell. The wing and rostral portions are dimensioned to provide limited overlapping coverage whereby the upper aspects of the parietal, temporal and frontal bones are only partially covered by the appliance in the protective position, thus allowing good air circulation and heat transfer over most of the infant's head, while preventing uneven contact of the relatively soft, compliant occipital areas against the sleep surface. The shell has a U-shaped cross-section, when taken through a horizontal section of the orthosis, and has bilateral symmetry. The shell (70) comprises a unitary molding formed of plastic material. The claimed method is anticipated by the normal use of the orthosis as disclosed by Clarren. Clarren further discloses s providing an inventory of protective appliances, in a variety of sizes that are indexed according to age, circumference and gender for the general infant population, measuring the circumference of an infant's head, and selecting the most closely matching protective appliance from the inventory.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pomatto in view of U.S. Patent Number 6,381,760 to Lampe et al.

Pomatto discloses the previously described cranial orthosis. Pomatto does not specify that the orthosis include a band connected to the rostral end portions and bridging across the forehead of the infant.

Lampe et al. disclose a cranial orthosis having a band of soft flexible material that bridges the forehead of a wearer, to remove sweat from the forehead. Lampe et al. specifies that the band comprise a layer of woven fabric material like open cell foam.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the orthosis disclosed by Pomatto, wherein the orthosis includes a band that bridges a wearer's forehead, as taught by Lampe et al., to absorb sweat from a wearer's brow.

Allowable Subject Matter

9. Claims 40-41 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays. The examiner's telephone number will change on 17 November 2004, to 571-272-4794.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda Wieker
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Examiner
Art Unit 3743

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